IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

IN RE: GENENTECH, INC.,	)	
HERCEPTIN (TRASTUZUMAB)	)	MDL DOCKET NO. 16-MD-2700
MARKETING AND SALES	)	ALL CASES
PRACTICES LITIGATION	)	

GENENTECH, INC.'S OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL REGARDING PREEMPTION DISCOVERY

Plaintiffs' fundamental claim is that Genentech expressly warranted that vials contained 440mg of Herceptin®[1] and breached the warranty by failing to provide 440mg.[2] This claim, if successful, would require Genentech to ensure that vials of Herceptin are filled with exactly 440mg of protein. Such a claim is preempted because it (1) directly conflicts with Congress's express determination to permit reasonable variations in the net contents of prescription drugs, and (2) requires a change in FDA-approved specifications that cannot be made without prior FDA approval. Phase 1 discovery then should address whether FDA permitted reasonable variations in the protein content of Herceptin®, and the specific FDA-approved specification. Genentech's previous productions fully address those issues and more.

Nevertheless, Plaintiffs seek discovery entirely unrelated to the content and concentration they allege. Such sweeping requests are not proportional to Phase 1 discovery and violate the boundaries permissible under Federal Rule of Civil Procedure 26(b). Plaintiffs assert that such expansive discovery is necessary because (1) "Genentech's past ability to change its label and prescribing information will inform Plaintiffs and the Court on the issue of whether Genentech

[1] Plaintiffs' allegations regarding concentration are inextricably tied to the content issue because the concentration of Herceptin® is a function of *both* the protein content of a vial *and* the amount of diluent added by the end user. Because FDA approved a range of protein content for Herceptin®, the resulting concentration also falls within a range.

[2] Plaintiffs' claims are not what Genentech could have stated but did not, nor what Genentech considered saying but did not.

can comply with both FDA regulations and state warranty laws," and (2) documents *may* show that Genentech decided to provide inaccurate information to the FDA. Neither of these arguments justifies the discovery sought.

DESCRIPTION OF GENENTECH'S PRODUCTIONS

Contrary to Plaintiffs' representations, Genentech has previously produced the documents applicable to its preemption defenses in this case (representing thousands of pages):

- The Chemistry, Manufacturing and Controls section of the initial Biologics License Application (BLA) for Herceptin® submitted to and approved by FDA, which contains detailed information about the manufacturing processes, formulas, FDA-approved specifications for Herceptin®, as well as responses to questions posed by FDA during its review.
- Prior Approval Supplements submitted to FDA in 2000, 2008, 2010, and 2013 seeking approval of new manufacturing sites for Herceptin® drug product for distribution in the United States (as well as amendments and approval letters), which contain detailed information about the manufacturing processes for Herceptin® drug product, FDA-approved specifications for Herceptin®, responses to questions posed by FDA during its review, and certain correspondence with FDA.
- Each version of the final labeling (i.e., prescribing information, carton label, and vial label) for Herceptin® distributed in the United States.
- Documents describing the test methods and procedures for determining protein content in Herceptin® vials prior to distribution.
- The Certificates of Analysis for each lot of Herceptin® distributed in the United States since January 1, 2010, which show the specific protein content for each such lot.

These documents contain all the information necessary for Plaintiffs—and, respectfully, the Court—to evaluate the protein content the FDA specification allows and the actual protein content in Genentech's vials.

REQUESTS REGARDING PAST LABEL CHANGES

Plaintiffs' broad requests for nearly twenty years of documents related to Herceptin®'s labeling seek vast quantities of information irrelevant to preemption or, indeed, to any issue in this lawsuit. As an initial matter, whether and how Genentech can modify the labeling for Herceptin® is purely a legal question governed by FDA regulations. Plaintiffs cannot convert it

into a factual issue by amassing evidence related to label changes unrelated to the content or concentration representations alleged (i.e., label changes unrelated to the merits of the case). Further, whether Genentech could have changed its label is irrelevant here because warranty claims are based on the warranty given, not whether a different warranty could have been given.

Moreover, Plaintiffs' requests go far beyond label changes and seek "all documents and communications concerning the Herceptin label and Prescribing Information for the years 1997 through the present."[3] These requests are not limited to the allegations regarding content or concentration at issue, nor to the time period after January 1, 2010 that Plaintiffs employ in other requests and a preservation letter.[4] They are thus directed not only to documents unrelated to preemption, but also to documents having nothing at all to do with the merits of this case.

Genentech has previously produced each version of the final labeling for Herceptin 440mg distributed in the United States. Despite having each version of the final label, Plaintiffs identify exactly one label change about which they make specific requests—the removal of a reference to a yield of 21mL of a multi-dose solution. Yet that change took place approximately a decade before the January 1, 2010 timeframe employed by Plaintiffs. And Plaintiffs fail to explain how a request for "all documents" related to it (or all changes)—including internal communications never considered by FDA—is proportional to Phase 1 discovery.

REQUESTS REGARDING WHETHER GENENTECH DEFRAUDED FDA

Plaintiffs attempt to justify their overly broad requests by claiming that they are "relevant

[3] *See* July 25, 2016 Letter § III (Pls.' Ex. 9). Similar requests seek "all correspondence between Genentech and the FDA relating to Herceptin's Labeling," "all documents relating to the FDA's approval of Herceptin Labeling," and "all 'Changes Being Effected' submitted to the FDA by Genentech relating to Herceptin." *See id*. at II-III.

[4] *See* Interrogatory No. 13 of the June 28, 2016 Discovery Requests (Pls.' Ex. 3) and counsel's June 10, 2015 document preservation letter (attached as Exhibit 1).

to assess whether Genentech provided accurate information to the FDA."[5] Plaintiffs cannot, however, oppose preemption by alleging fraud on the FDA, which is itself preempted. Under Supreme Court precedent, fraud-on-the-FDA claims are preempted because they "inevitably conflict with FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). Such claims are therefore irrelevant to a preemption analysis and cannot justify the discovery sought. *See, e.g.*, *In re Incretin Mimetics Prods. Liab. Litig.*, MDL Case No. 13md2452, 2014 WL 4987877, at *3-4 (S.D. Cal. Oct. 6, 2014) (denying discovery directed to fraud on the FDA as irrelevant to preemption) (attached as Exhibit 3).[6]

The documents already produced by Genentech reflect not only the FDA-approved specification for protein content (a range unchanged since FDA approval in 1998), but also the protein content of each lot of Herceptin® to which Plaintiffs' claims could possibly relate. To the extent Plaintiffs seek discovery beyond the already-produced submissions considered by FDA in approving the applicable specifications for Herceptin® protein content, they represent a backdoor attempt at full-blown merits discovery.[7] Expansive discovery of correspondence and internal documents cannot be what the Court contemplated for limited Phase 1 discovery.

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[5] The email relied on by Plaintiffs does not reflect fraud on the FDA. In fact, the email discusses a technical report supporting studies for an Investigational New Drug (IND) application to FDA. Moreover, because FDA approved a range of protein content for Herceptin®, the resulting concentration also falls within a range. This should be no surprise given that the carton and vial labeling for Herceptin during the relevant timeframe state the concentration is "***approximately*** 21 mg/mL." *See, e.g.,* GENE-FL-000000100 and GENE-FL-000000007-9 (attached as Exhibit 2) (emphasis added). Even if the 21.8 mg/mL concentration Plaintiffs allegedly obtained is accurate, it is still approximately 21 mg/mL.

[6] See also *In re Bextra and Celebrex Mktg. Sales Practices and Prod. Liab. Litig.*, No. M:05-1699, 2006 WL 2374742, at *10 (N.D. Cal. Aug. 16, 2006) (holding that plaintiffs' allegation that defendant withheld material data from the FDA does not change the preemption analysis).

[7] Plaintiffs' requests seek (1) "all documents and communications related to the FDA approval process for Herceptin," (2) "all documents and communications between Genentech and any person concerning the mass, volume, or density of the medicine available in a Herceptin vial," (3) "all studies related to the mass, volume, or density of the medicine in a Herceptin vial," (4) "all documents concerning the density of multidose Herceptin if the medicine is reconstituted

MISCELLANEOUS

- Plaintiffs attempt to justify interrogatories seeking identification of individuals involved with various aspects of Herceptin® approval, labeling, and testing over the course of nearly twenty years using the same arguments addressed above.
- Plaintiffs' Motion misrepresents the details of Genentech's identification of its expert. Case Management Order No. 1 (filed June 24, 2016) required Genentech to identify each person it "already expects to rely on as an expert on federal preemption issues by June 24, 2016." As reflected in correspondence from counsel, Genentech was still considering its expert selection as of June 24, but had finalized that selection and provided identifying information by June 30.
- Plaintiffs assert that they must be permitted discovery on any *possible* preemption argument Genentech could raise because they have not seen the preemption motion. Although Genentech's preemption arguments are summarized in its submission in support of an early summary judgment motion (*see* Genentech, Inc.'s Submission in Support of Early Motion for Summary Judgment on Federal Preemption (submitted June 20, 2016)) and in its July 19, 2016 letter (Pls.' Ex. 8), if reviewing the preemption motion would assist Plaintiffs to appropriately tailor their requests, perhaps this Motion should be deferred for the three weeks until Genentech's filing.

CONCLUSION

Genentech requests that the Court deny Plaintiffs' Motion because the discovery at issue (1) is not limited to information and documents that reasonably might bear on preemption, (2) relates to preempted and unsupported fraud-on-the-FDA allegations, and (3) far exceeds the subject matter and timeframe at issue in this case.

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following the directions in the Prescribing Information," (5) "all draft versions of the 'Chemistry, Manufacturing and Controls' section of the Herceptin Biologics License Application submitted to the FDA by Genentech," and (6) "the results of all testing and measurements done to determine the concentration of the reconstituted Herceptin solution in each vial of the drug." *See generally* July 25, 2016 Letter §§ III-IV (Pls.' Ex. 9).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 1st day of August, 2016 the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

s/William W. O'Connor
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